Background: The problem of medication error (ME) has attracted worldwide interest in recent years since it is causing a significant morbidity and mortality, and therefore generates an additional economic cost for health care systems. In Morocco, a prospective multicenter study conducted in 2007 at Rabat University, found that the frequency of ME was 7.8% in pediatric intensive care and 7.3% in adults intensive care.<sup>[2]</sup>

Case report: It was 9 years old child with no medical history who has suffered for some years of enuresis. The child received medical treatment prescribed by an urologist based of oxybutynin chloride 5 mg at a rate of half a tablet three times daily for a month. The child has doubled the dose and took one tablet three times daily for 3 consecutive days and developed an acute urinary retention which required a urinary catheter in an emergency. The child after urinary catheter has kept dysuria and fifth days of drug discontinuation, he developed a second acute urinary retention with big urinary bladder distension. The evolution was slowly favorable with persistent episodes of dysuria.

Discussion: Oxybutynin chloride is an anticholinergic antispasmodic drug. It decreases the contractility of the detrusor and so decreases the amplitude and frequency of bladder contractions and the intravesical pressure. The causality assessment of the ADR was plausible with French method, and the side effect was evitable because the error was due to poor observance. The pharmacokinetic properties are useful to know to understand the clinical chronology of the drug. After oral administration, Oxybutynin is rapidly absorbed and has an extensive first pass hepatic metabolism. So the absolute systemic bioavailability is only 6.2%. The major metabolite is pharmacologically active (desethyloxybutynin). Oxybutynin is biexponential eliminated and less than 0.02% of the administered dose is excreted in the urine. Excretion is mainly hepatobiliary and half-life is only 2 hours. The persistence of the ADR could be due partly to the low hepatobiliary clearance although the drug has a short half-life, and secondly because the main metabolite is active with large interindividual variations.

Conclusion: The medication errors in children can be harmful and involve life-threatening. The pharmacokinetic profile of some drugs complicate sometimes the clinical situation.

## References

- 1. Kaushal R, Bates DW, Landrigan C, et al. Medication Errors and Adverse Drug Events in Pediatric inpatients. JAMA 2001; 285 (16): 2114-2120
- Benkirane R, Abouqal R, Haimeur C, et al. Incidence of Adverse Drug Events and Medication Errors in Intensive Care Units: A Prospective Multicenter Study. Journal of Patient Safety 2009; 5 (1): 16-22

## PP103. Therapeutic Errors in Older Adults

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**Objectives:** To evaluate the reasons for unintentional therapeutic errors in older adults, the types of medications most frequently involved, and the medical outcomes related to these adverse drug events.

Design: Retrospective analysis of department of Pharmacology, university hospital Ibn Rochd of Casablanca.

Setting: Collects data from January to December 2010 were examined collected from different departments of medicine and surgery.

Participants: Cases involving adults aged 65 and older with a potentially toxic exposure due to unintentional therapeutic errors.

Measurements: Hazard factor analysis was conducted to identify medications that pose risk in this population.

Results: There were 98 for 302 older adults with reported therapeutic errors, of which 72 cases were followed to a known medical outcome. A major effect or death occurred in 46 cases. The most common reasons for therapeutic errors were inadvertently took or given medication twice, wrong medication taken or given, and other incorrect dose. The reasons associated with the highest rate of major effect or death were drug interaction, health professional or iatrogenic error, and more than one product containing same ingredient. Certain medication classes such as antipsychotics, analgesics, anticoagulants, antidiabetics and some cardiovascular agents were associated with high hazard feature.

Conclusion: Evaluate therapeutic errors in older adults was very interesting to identify reasons associated with frequently reported errors, as well as reasons and medications involved with errors that result in serious outcomes. Knowing the reasons why they occur can aid in developing strategies for decreasing unintentional errors in older adults.

#### References

- 1. Hajjar ER, Hanlon JT, Artz MB, et al. Adverse drug reaction risk factors in older outpatients. Am J Geriatr Pharmacother 2003; 1: 82-9
- 2. Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006; 296: 1858-66
- Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003; 289: 1107-16
- Cobaugh DJ, Krenzelok EP. Adverse drug reactions and therapeutic errors in older adults; A hazard factor analysis of poison center data. Am J Health Syst Pharm 2006; 63: 2228-34

## PP104. A Pilot Prospective Observational Hospital Study on Adverse Drug Reactions due to Medication Errors

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Background: A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient.<sup>[1]</sup> It has been estimated that 1–2% of patients admitted to US hospitals are harmed as a result of medication errors.<sup>[2]</sup> Prescribing faults and prescription errors are the major problem among medication errors. In fact, prescription errors account for 70% of medication errors that could result in adverse drug reactions (ADRs).<sup>[3]</sup>

Objective: We performed a pilot prospective observational study on adverse drug reactions due to medication errors occurred in patient aged >18 years hospitalized in an Internal Medicine Unit of Verona University Hospital from April 2010 to June 2010.

Methods: The project was of three phases. In the first one three physicians of involved unit reviewed all patient charts and registered all ADRs. A panel of experts evaluated if the ADRs were due to medication errors or not, and in the case of error they identified the cause. In the second phase educational audits directed to health professionals have been organized and tools (e.g. check-list) to reduce the medication

errors have been proposed. The third phase, that is similar to the first one and takes account of tools, is in progress.

Results: Preliminary results showed that, from 14 April 2010 to 22 June 2010, 145 patients (median age 73.6, 51% female) have been enrolled. Twenty—six patients (18%) had at least one ADR occurred during the hospitalization. The total number of ADRs occurred during the hospitalization was 32. A panel of experts evaluated that 14 ADRs (44%) were due to medication errors, out of which 50% were serious. The most frequent ADRs caused by a medication error was hypotension and the drugs most involved were: amlodipine, heparin, furosemide, ramipril, morphine and electrolyte solution.

Conclusion: This pilot study confirms the high incidence of medication errors as cause of ADRs.

Therefore the prevention of medication errors is an important task to improve health patient and to reduce the health care costs. Strategies, such as a prescription check list, can be adopted to try to minimize risks.

#### References

- 1. Aronson JK, Br J Clin Pharmacol 2009; 67 (6): 599-604
- 2. Barber ND, Dean BS. Clin Risk 1998; 4: 103-6
- 3. Velo GP, Minuz P. Br J Clin Pharmacol 2009; 67 (6): 624-8

## PP105. Preventability Analysis of Adverse Drug Reactions Detected by Stimulated Spontaneous Reporting in Two Internal Medicine Departments in Romania

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Objectives: Serious adverse drug reactions (ADRs) in hospitalized patients are common and often preventable. In a prospective study conducted over a 12-month period in an internal medicine department in Romania, using stimulated spontaneous reporting for identifying ADRs, the overall incidence of serious ADRs in the hospitalized patients was 4.7%. Out of total ADRs 50% were considered preventable. In our objective was to analyse preventability data on previous collected ADRs that are stored in our database in order to identify the most common drugs involved in ADRs and the prescription patterns with the final goal of proposing preventing strategies.

Methods: The first two hundred ADRs detected in the internal medicine departments and stored in our database were characterized by drug, drug class, severity, probability of causality, duration, outcome and preventability. Drug-drug interactions, inappropriate dose, offlabel use, contraindications, according to the Summary of the Product Characteristics (SmPC) and Thomson Micromedex were the factors assessed for preventability. Patient-related factors like hepatic or renal dysfunction, allergy history, self-medication, non-adherence were also evaluated.

Results: 43% of the total ADRs were considered preventable. Anti-coagulants (16%), followed by NSAIDs (15.5%), antibiotics (11.5%) and diuretics (9.5%) were the drugs most common involved in preventable ADRs. The ADRs that were considered preventable are as follows: gastrointestinal ADRs (20.93%), renal ADRs (13.95%), metabolic ADRs (12.79%), vascular (11.62%) and hepatic (8.13%) ADRs. In 58% of the cases of preventable ADR, they lead to the hospitalization of the patient. Drug-drug interactions (DDIs), inadequate dose, self medication, inadequate drug therapy monitoring and contraindications were the factors leading to preventable ADRs. In 14.5%

cases of preventable ADRs there are clear warnings in the SmPC regarding the adverse effects. 87.2% of all preventable ADRs were type A adverse reactions.

Conclusions: Four groups of drugs account for more then half of the preventable ADRs. Moreover the two leading causes of preventable ADRs are DDIs and inadequate dose. Preventing strategies should target drug prescription.

### References

- Lagnaoui R, Moore N, Fach J, et al. Adverse drug reactions in a department of systemic disease-oriented internal medicine: prevalence, incidence, direct costs and avoidability. Eur J Clin Pharmacol 2000; 55: 181-6
- 2. Farcas A, Sinpetrean A, Mogosan C, et al. Adverse drug reactions detected by stimulated spontaneous reporting in an internal medicine department in Romania. Eur J Intern Med 2010; 21 (5): 453-7

# PP106. Omitted Doses in a Paediatric Intensive Care Unit: A Pilot Study

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Objectives: Medication errors are more common in paediatric intensive care units (PICU),<sup>[1]</sup> and omitted doses are a major concern within the UK.<sup>[2,3]</sup> The objective was to measure the incidence and nature of omitted doses on a PICU (paediatric intensive care unit) and assess the potential clinical significance of these omissions.

Method: A prospective collection of all drug administrations on the ward during a 14 day study period. Administered doses were compared with prescribed doses. Data was recorded on a standardised data capture form. The frequency of dose omissions was calculated as the sum of omitted doses divided by total prescribed doses. Dose omissions were classified by a panel of specialist paediatricians, using a questionnaire with a 5-point Likert scale. The classification was based on the National Reporting & Learning Services (NRLS) severity rating scale of patient safety incidents. [4] Potential clinical significance levels for each omission were then decided by consensus of the panel.

Results: 1995 doses were prescribed, of which 129 (6.5%) doses were omitted. The most common types of drugs that were omitted were: anti-infectives (20.2%), IV nutrition & IV fluids (15.5%), minerals (15.5%), diuretics (14.7%) and analgesics (9.3%). Less common drugs omitted included: antisecretory drugs (3.88%), laxatives (2.33%), bile acids (1.5%), hypnotics (3.1%), anti-epileptics (1.5%), anti-thyroid drugs (0.8%), corticosteroids (0.8%) and probiotics (1.5%). The dominant reason for dose omissions was intentional omission, with no documented reason (64%). Authorised omissions include: 'at doctor's request' (12.%), intentional omission: 'awaiting blood levels' (1.5%), and 'patient cannot receive' (fasting/vomiting/no access) (12.%). Cumulatively, authorised omissions made up 26% of omissions. Unauthorised omissions included 'drug not available' (3%), intentional omission with no reason given, (64%), 'patient away from ward' (3%) and a blank space in chart - no reason given at all (3.88%). Unauthorised omissions accounted for 74% of omissions. 44% of omissions involved low potential harm to patient, potentially resulting in observation, 31% involved moderate potential harm, which may cause a moderate increase in treatment and 20% of omissions involved severe potential harm, with potential to cause permanent patient harm.